

Sub DI
C 1
8 biological sample derived from the subject, wherein the LSD marker is selected from the group
9 consisting of Lamp-1, Lamp-2, Limp-II, mannose-6-phosphate receptors, α -L-iduronidase, 4-
10 sulphatase, acid phosphatase (ACP), β -hexosaminidase, and α -mannosidase, [or an
11 **immunologically interactive homologue, analogue or derivative thereof**], a difference in
12 the level of the LSD marker in the subject relative to the corresponding level of the LSD
13 marker in a non-affected individual or population being indicative of a LSD.

53. (Once amended) The method according to claim 52, wherein the LSD
marker is selected from the group consisting of Lamp-1, Lamp-2 and Limp-III, **or an**
immunologically interactive homologue, analogue or derivative thereof.

54. Cancelled.

Sub E2
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55. (Once Amended) The method according to claim [54] 53, wherein the
LSD marker is Lamp-1.

56. (Once Amended) The method according to claim [54] 53, wherein the
LSD marker is Lamp-2.

57. (Once Amended) The method according to claim [54] 53, wherein the
LSD marker is Limp-II.

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58. The method according to claim 52, wherein the biological sample comprises blood, plasma,
urine, a fibroblast cell, a fibroblast cell culture or a fibroblast cellular extract.

59. The method according to claim 54, wherein the biological sample comprises blood, plasma,
urine, a fibroblast cell, a fibroblast cell culture or a fibroblast cellular extract.

60. The method according to claim 59, wherein the biological sample comprises blood, plasma or
urine.

Sub G2
61. The method according to claim 59, wherein the fibroblast cell or fibroblast cell culture is a skin
fibroblast or skin fibroblast cell culture or a cellular extract thereof.

62. The method according to claim 61, wherein the fibroblast cell, fibroblast cell culture or fibroblast
cellular extract is a Pompe, Salla, MPS II or MPS VI fibroblast cell, cell culture or cellular extract.

63. The method according to claim 52, wherein the LSD is selected from the list set forth in Table 1.

NE 35 ~~Sub 92~~ 64. The method according to claim 63, wherein the LSD is selected from the group consisting of
36 MPS I, MPS II, Gaucher disease, Pompe disease and Salla's disease.

C 3 37 ~~Sub 92~~ 65. (Once amended) The method according to claim 52, wherein the step of
38 assaying the level of a[n] LSD marker comprises measuring the enzyme activity of said LSD
39 marker in the biological sample.

40 66. (Once amended) The method according to claim 52, wherein the step of
41 assaying the level of a[n] LSD marker comprises contacting the biological sample with one or
42 more immunointeractive molecules specific for said LSD marker for a time and under
43 conditions sufficient for the formulation of a complex to occur.

44 67. The method according to claim 66, wherein the immunointeractive molecule is an antibody
45 molecule that binds to the LSD marker.

46 68. The method according to claim 67, wherein the antibody molecule is a monoclonal antibody that
47 binds to the LSD marker.

NE 48 69. The method according to claim 66, wherein the immunointeractive molecule is labeled with a
49 reporter molecule.

50 ~~Sub 92~~ 70. The method according to claim 66, further comprising the step of contacting the complex formed
51 between the LSD marker and the immunointeractive molecule with a labeled immunointeractive molecule for a time and under
52 conditions sufficient for binding to occur.

53 71. The method according to claim 70, wherein the labeled immunointeractive molecule is labeled
54 with a reporter molecule.

55 72. The method according to claim 69, wherein the reporter molecule is an enzyme, a fluorophore or
56 a radionuclide molecule.

57 73. The method according to claim 72, wherein the enzyme, fluorophore or radionuclide molecule is
58 selected from the group consisting of horseradish peroxidase, glucose oxidase, β -galactosidase, alkaline phosphatase,
59 fluorescein, Eu³⁺ and other lanthanide metals, and rhodamine.

60 74. (Once amended) The method according to claim 52, wherein:

- 61 ~~Sub 94~~ (a) the LSD is selected from the list set forth in Table 1;
62 (b) the LSD marker is selected from the group consisting of LAMP-1,
63 LAMP-2, and LIMP-II;

- 64 *Sub Dg* (c) the biological sample comprises blood, serum or urine; and
65 *cont* (d) the assay comprises measuring the enzymatic activity of the LSD marker
66 or is an immunoassay.

67 75-92. Cancelled

Sub Dg
69 93. (Once amended) A method for detecting a lysosomal storage disorder
70 (LSD), comprising assaying LAMP-1, LAMP-2 or LIMP-II in a sample of blood obtained
71 from a patient that is asymptomatic for a LSD, a difference in the level of LAMP-1, LAMP-2
72 or LIMP-II in the patient relative to the corresponding level of LAMP-1, LAMP-2 or LIMP-II
in a non-affected individual or population being indicative of a LSD.

73 94. (Once amended) The method according to claim 93, further comprising
74 determining whether the level of LAMP-1, LAMP-2 or LIMP-II in the patient is elevated
75 relative to the corresponding level of LAMP-1, LAMP-2 or LIMP-II in [a control] the non-
76 affected individual or population.

REMARKS

Claims 52-94 are pending. Claims 54 and 75-92 are cancelled in this amendment without prejudice or disclaimer. These claims are cancelled solely to advance prosecution of other important subject matter. Applicants reserve the right to reinstate these claims or to pursue these claims in another application.

I. Rejection of Claims 52-74 and 84-92 under 35 U.S.C. § 112, first paragraph

In the Office Action, it is stated that recitation of the terms immunologically active homologue, analogue or derivative thereof in reference to a LSD marker is not adequately described such that the claims are properly enabled. Applicants respectfully disagree; nonetheless, in order to advance prosecution, the cited phrase has been deleted from the relevant claims (claim 52 and 53). Claims 84-92 are cancelled by this amendment; thus, this ground of rejection is rendered moot with respect to these claims.